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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,990	07/28/2003	Dietrich Wilhelm Schacht	25352	4266

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
08/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,990	SCHACHT ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending in this application.

Action Summary

1. The objection of claims 1-12 for containing informalities is hereby withdrawn in view of applicant amendment filed March 5, 2007.

2. The rejection of claims 11-13 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn in view of applicants amendment filed March 5, 2007.

3. The provisional rejection of claims 1, 2, 5-7 and 10-14 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending application 10/623,864 is being maintained for the reasons stated in the office action dated September 5, 2006.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 2, 5-7 and 10-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/623,864. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applicants are directed towards a transdermal delivery system comprising a backing layer, a self-adhesive matrix containing a drug and a protective foil or sheet. The difference between the tow applications is that in claim 1 of the instant application ('990) the drug is the broad category of amine-functional drugs and the drug of the copending application ('864) is specific to rotigotine. However, depending claims 5-7 of the instant application ('990) discloses that rotigotine is a suitable drug to be used in the system and thus is obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

5. Applicant will file a terminal disclaimer when allowable subject matter is indicated.

6. The rejection of claims 1-14 under 35 U.S.C. 103(a) over Zaffaroni (3,797,494) in view of Lee et al. (5,500,222), Klose et al. (2004/0013620), Colley et al. (5,217,718) and Goodman and Gilmans (1990) is being maintained for the reasons stated in the office action dated September 5, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni (US 3,797,494) in view of Lee et al. (US 5,500,222), Klose et al. (US 2004/0013620), Colley et al. (US 5,217,718) and Goodman and Gilmans (1990).

Applicants claim a transdermal delivery system (TDS) comprising a backing layer, a self-adhesive matrix containing a drug and a protective foil or sheet, wherein the matrix contains the drug in microreservoirs.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Zaffaroni discloses in figures 1-5, specifically figures 4 and 5 an adhesive bandage having a backing layer and microcapsules of drug distributed throughout the adhesive layer (col. 9, lines 54-62). Column 10, lines 32-34 teach that the microcapsules have an average particles size from several tenths of a micron to 5,000 microns. Column 12, lines 9-67 described the various drug classes, which can be employed in the transdermal system. Column 14, line 60 through column 15, lines 20 teach examples of adhesives which may be employed in the system of which a silicone-type i.e. silicone rubber is taught. Column 15, lines 58-65 teach applying the bandage to the affected area of the patients skin.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The prior art reference of Zaffaroni does not teach the log p or the pKa values of the amine-functional drug or the specific drugs as claimed. It is not taught by Zaffaroni the matrix comprising two or more silicone adhesives. It is for this that Lee et al., Klose et al. Colley et al. and Goodman and Gilmans are joined.

Lee et al. disclose that oxybutynin can be administered via a transdermal delivery system.

Klose et al. teach a transdermal delivery of anti-Parkinsons agents wherein rotigotine is disclosed (paragraph [0026]).

Colley et al. disclose a transdermal delivery device wherein the pressure adhesive can be polysiloxanes, silicones, polyacrylates, etc. or mixtures thereof (col. 6, lines 20-38).

Goodman and Gilmans teaches that tertiary amines such as oxybutynin can be used for their antispasmotic properties (page 160).

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Lee et al., Klose et al., Colley et al. and Goodman and Gilmans with Zaffaroni to arrive at the claimed invention. Column 14, lines 60-62 teach that any well-known dermatologically acceptable pressure sensitive adhesives can be used in the claimed system. One of ordinary skill in the art could use the teachings of Colley et al. describing the use of silicones or mixtures thereof as the adhesive when formulating the TDS of the instant invention to optimize the performance of the drug-adhesive matrix. Zaffaroni et al. disclose in column 12, line 38, the use of antispasmotic agents in the TDS. Goodman and Gilmans is relied upon to teach that oxybutynin can be used as an antispasmotic agent, and since Zaffaroni teaches the broad category of antispasmotic agents, the use of oxybutynin would have been obvious to one of ordinary skill in the art. Although the prior art mentions atropine,

methscopolamine, etc. in the reference, it is only a small representation of the broad category. Lee et al. is relied upon to teach that oxybutnin can be delivered via a TDS. Klose et al. is relied upon to teach that rotigotine can be administered via transdermal delivery. One of ordinary skill in the art would be motivated to incorporate an anti-Parkinson agent into a TDS for the purposes of providing a sustained release of the agent to the patient in need thereof. With respect to the claimed log p or the pKa values of the amine-functional drug, absent a clear showing of criticality, the determination of the particular log p or the pKa values of the amine-functional drug is within the skill of the ordinary artisan as part of the process of normal optimization to achieve the desired results of the claimed composition.

Response to Arguments

8. Applicant's arguments filed March 16, 2007 have been fully considered but they are not persuasive.

Applicant argue that the combination of Zaffaroni , Lee et al., Klose et al., Colley et al. and Goodman and Gilmans do not disclose the claimed invention. Applicant argues that Zarraroni does not teach that the amine functional drug is in its free base form. The examiner disagrees. Zarraroni teaches an amine functional drug which can be used in its free base form, i.e. nitroglycerin (col. 12, line 36) in a transdermal device. The applicant also argues that the combination of the references is based upon hindsight reconstruction. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be

recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

9. Claims 1-14 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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